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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,526	07/07/2005	Stephen Robert Bloom	AI 9250US	6041

23579 7590 10/26/2006

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/541,526	BLOOM ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 38-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 38-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 38-61 are pending and require restriction.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 38-47, drawn to composition comprising oxyntomodulin and one or more additional agents which influence weight and/or food intake.

Group II, claim(s) 48-50 and 52-61, drawn to a method for decreasing calorie intake, decreasing appetite, decreasing food intake, and controlling one or more of appetite, satiety and hunger in a subject, comprising administering oxyntomodulin and one or more additional agents.

Group III, claim(s) 48 and 52-61, drawn to a method for increasing energy expenditure in a subject and to a method for alleviating a condition or disorder in a subject, which can be alleviated by reducing nutrient availability and/or by increasing energy expenditure, comprising administering oxyntomodulin and one or more additional agents.

Group IV, claim(s) 48 and 52-61, drawn to a method for weight control or treatment, reduction or prevention of obesity, preventing and reducing weight gain, inducing and promoting weight loss and reducing obesity as measured by the BMI in a subject, comprising administering oxyntomodulin and one or more additional agents.

Group V, claim(s) 48, 52, 53, 58 and 59, drawn to a method for improving lipid profile in a subject, comprising administering oxyntomodulin and one or more additional agents.

Group VI, claim(s) 48 and 52-61, drawn to a method for reducing levels of circulating ghrelin in a subject, comprising administering oxyntomodulin and one or more additional agents.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Annex B, Part I(f) of the Administrative Instructions under PCT states that, "wherein a single claim defines alternatives (chemical or non-chemical)...the requirement of a technical

interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature."

The alternatives must comply with subsections (i)(A) and one of either (i)(B)(1) or (i)(B)(2), which requires that, "all alternatives have a common property or activity" and "a common structure is present, i.e., a significant structural element is shared by all of the alternatives" (B)(1) or "in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains."(B)(2).

In the instant case, as evidenced by the claims themselves, having different methods with different desired outcomes, does not require that the compounds have the same activity/function, failing to satisfy requirement (A). Additionally, assuming *arguendo* that the function is common, the claim fails to satisfy either (B)(1) or (B)(2). The claim recites no common structure that is shared by all the alternatives, thus failing to meet the requirements of (B)(1) as oxyntomodulin is defined in the specification (paragraphs 42-46) as:

> The term OXM used in this text also covers any analogue of the above OXM sequence, wherein the histidine residue at position 1 is maintained or replaced by an aromatic moiety carrying a positive charge or a derivative thereof, preferably wherein the moiety is an amino acid, more preferably wherein it is a histidine derivative, while 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22 of the other amino acids in the above OXM sequence can be independently replaced by any other independently chosen amino acid, with the exception of histidine in position 1.
> Any one or more (to 22) other alpha-amino acid residue in the sequence can be independently replaced by any other one alpha-amino acid residue. Preferably, any amino acid residue other than histidine is replaced with a conservative replacement as well known in the art i.e. replacing an amino acid with one of a similar chemical type such as replacing one hydrophobic amino acid with another.
> As discussed above, 1 to 22 of the amino acids can be replaced. In addition to the replacement option above, this may be by a non-essential or modified or isomeric form of an amino acid. For example, 1 to 22 amino acids can be replaced by an isomeric form (for example a D-amino acid), or a modified amino acid, for example a nor-amino acid

(such as norleucine or norvaline) or a non-essential amino acid (such as taurine). Furthermore, 1 to 22 amino acids may be replaced by a corresponding or different amino acid linked via its side chain (for example gamma-linked glutamic acid). For each of the replacements discussed above, the histidine residue at position 1 is unaltered or defined above.
In addition, 1, 2, 3, 4 or 5 of the amino acid residues can be removed from the OXM sequence with the exception of histidine at the 1 position (or as defined above). The deleted residues may be any 2, 3, 4 or 5 contiguous residues or entirely separate residues. The C-terminus of the OXM sequence may be modified to add further amino acid residues or other moieties.

Thus, there is no common core structure, as the specification provides that OXM is a generic term that includes derivatives and analogs of no defined structure. Further, in looking to subsection (f)(iii), it is stated that 'recognized class of chemical compounds' means that, "there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved." One of skill in the art would not recognize these divergent compounds to function in the context of the instantly claimed invention. Thus, the claim fails to meet the requirement of (B)(2) and the species lack unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: The claims are generic to a myriad of species embraced by oxyntomodulin, too numerous to recite individually, as shown above, and to the 'one or more additional agents' in the composition and being administered in the methods.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons set forth *supra* in showing a lack of unity in the inventions.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Please note, the methods do not currently require the use of the products of Group I, *per se*, as evidenced by claim 61, which clearly indicates that the compounds need not be in the same composition and are administered sequentially. Thus, the methods would not be rejoined in accordance with rejoinder practice unless amended during prosecution as required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached at (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew D Kosar 10/23/06

Andrew D Kosar, Ph.D.
Patent Examiner
Art Unit 1654